K000450

JUL 1 8 2000

IX. 510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical 150 Glover Avenue Norwalk, CT 06856
CONTACT PERSON:	Christopher A. Graham
DATE PREPARED:	May 5, 2000
CLASSIFICATION NAME:	Implantable Clip
COMMON NAME:	Implantable Clip
PROPRIETARY NAME:	Auto Suture* Micro SURGICLIP* Clip Applier
PREDICATE DEVICES:	Spetzler-Taka Micro-Ligation Clip™ (K991002), Weck Hemoclip Ligating Clip (K841547), and Auto Suture* Vascular Anastomosis Clip** (K933887)
DEVICE DESCRIPTION:	The Auto Suture* Micro SURGICLIP* clip applier consists of a rotating shaft and an integral cartridge containing titanium clips. The clip is placed around a vessel or other tubular structure. As the levers of the clip applier are squeezed together, the clip is closed around the vessel or structure. As the levers are released, a new clip is automatically loaded into the clip applier jaws. The Micro SURGICLIP* clip applier is available in three (3) sizes: medium, large and extra large.
INTENDED USE:	The Auto Suture* Micro SURGICLIP* clip applier has applications in many types of surgical procedures for radiographic marking and temporary or permanent occlusion of vessels and other tubular structures, including intracranial blood vessels.
MATERIALS:	All component materials of the Auto Suture* Micro SURGICLIP* clip applier are comprised of materials which are in accordance with ISO Standard # 10993-1.
PERFORMANCE DATA:	In-vivo and In-vitro testing was performed to verify that the Auto Suture* Micro SURGICLIP* clip applier was substantially equivalent to the predicate devices in occluding blood vessels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2000

Mr. Christopher A. Graham
Program Manager, Regulatory Affairs
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K001450
Trade Name: Auto Suture Micro SURGICAL Clip Applier
Regulatory Class: II
Product Code: FZP
Dated: May 5, 2000
Received: May 8, 2000

Dear Mr. Graham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications For Use:

510(k) Number (if known): K001450

Name: Auto Suture* Micro SURGICLIP* Clip Applier

Indications For Use:

The Auto Suture* Micro SURGICLIP* clip applier has applications in many types of surgical procedures for radiographic marking and temporary or permanent occlusion of vessels and other tubular structures, including intracranial blood vessels.

(Please do not write below this line - continue on another page ~~if needed~~)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR §801.109)

Donna R. Bochman
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001450